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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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TOWNSEND AND TOWNSEND AND CREW, LLP
 TWO EMBARCADERO CENTER
 EIGHTH FLOOR
 SAN FRANCISCO, CA 94111-3834

EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,434

Applicant(s)

PETERSEN ET AL.

Examiner

Nelson Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-75 is/are pending in the application.
- 4a) Of the above claim(s) 41-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 41-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's cancellation of claims 1-20 and addition of claims 21-75 are acknowledged and have been entered.
2. Claims 21-75 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 21-40, drawn to a device comprising a lysing chamber containing capture material, classified in class 435, subclass 283.1.
 - II. Claims 41-56, drawn to a device for extracting nucleic acid, classified in class 435, subclass 286.5.
 - III. Claims 57-75, drawn to a device for extracting nucleic acid, classified in class 435, subclass 287.2.
4. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions: group I is directed toward extracting an analyte, while group II is directed toward extracting nucleic acids, and involves a binding material for binding nucleic acid and group III is directed toward extracting nucleic acids and involves a removal material for holding unwanted material.

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5. Newly submitted claims 41-75 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 41-56 claim a lysing chamber containing a capture material, which is broader in scope than the filter claimed in the original invention, as well as a binding material for binding nucleic acid, which was not recited in the original invention. Claims 57-75 claim a lysing chamber containing capture material, which is broader in scope than the filter claimed in the original invention, as well as a removal material for holding unwanted material, which was not recited in the original invention. With respect to claims 21-40, even though applicant has broaden the scope of the filter to a capture material, support in the specification for capture material only encompasses filters, and therefore claims 21-40 would have the same scope as the original claims

6. Since applicant has received an action on the merits for the originally presented invention, which has the same scope of group I, claims 21-40, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-75 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Withdrawn

7. Applicant's arguments, see pages 12-14, filed March 24, 2004, with respect to the rejection of claims 1-20 under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) have been fully considered and are persuasive. The rejection of claims 1-20 under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) has been withdrawn.

Claim Rejections - 35 USC § 112

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8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 21, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. Claim 21, 40 recite the limitation that "the lysing chamber contains capture material for capturing cells or viruses". However, in the original claims, applicant recited that the cartridge contained "at least one filter for capturing the cells or viruses", which is a narrower limitation. Furthermore, in the specification, applicant does not provide support for any other types of capture material other than filters and beads.

11. Claims 38 and 39 recite the limitation that the beads for rupturing cells or viruses recited in claim 36 also have a binding affinity for the cells or viruses to be disrupted or for the analyte. However, the specification teaches that the beads having a binding affinity for the cells or viruses are different from the beads for rupturing cells or viruses.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 21-23, 31, 33-36, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Buechler et al [US 6,106,779] and Murphy et al [US 5,374,522].

With respect to claims 21, 33-36, 38-40, Wilding et al teach a cartridge having a sample flow path (claim 1), lysing means (claim 2), filters (column 13, line 41 - column 14, line 13), beads for binding viruses and cell types (column 3, lines 58-62, column 13, lines 1-5), a waste chamber in fluid communication with the lysing chamber (column 13, lines 13-16), which has an external surface (figures 1, 2), a third chamber (PCR chamber) connected to the lysing means via an analyte flow path for receiving the analyte separated from the sample (claims 1-4), and a flow controller comprising valves that direct fluid flow in the system (claims 2, 3, column 14, lines 14-40). Wilding et al fail to teach that the filter or beads are contained in the lysing means.

Buechler et al, however, teach that the use of filters and meshes for the lysing of cells and for removing component material (column 23, lines 10-35). Murphy et al teaches that beads can be used for lysing cells without destroying the RNA and DNA once released when subjected to ultrasonic energy from a transducer (column 5, lines 5-20, claim 1). Therefore it would have been obvious in the method of Wilding et al to include filters, as suggested by Buechler et al, or beads, as suggested by Murphy et al, in the lysing chamber, for lysing cells while also removing component material, or for lysing cells without destroying the RNA and DNA once released when subjected to ultrasonic energy from a transducer.

14. With respect to claim 25, Wilding et al teach a means for thermally regulating the contents of said chamber whereby the temperature is controlled to amplify said preselected

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polynucleotide (claim 8) and at least one optical detector for detecting the analyte (column 4, lines 46-62).

15. With respect to claim 31, Wilding et al teach sample chambers having a port for introducing a sample into the cartridge, a sample flow path, and a lysing chamber in the sample flow path (columns 15-16, example 2, fig. 12).

16. Claims 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Buechler et al [US 6,106,779] and Murphy et al [US 5,374,522], as applied to claims 21 and 22 above, and further in view of Nelson et al [US 5,660,029].

Wilding et al teach a cartridge with a reaction chamber for amplifying the analyte (claim 3, 4) and gel electrophoresis area (column 4, lines 46-62). Wilding does not specifically teach the use of a capillary electrophoresis area.

Nelson et al, however, teaches that benefits of capillary electrophoresis include rapid run times, high separation efficiency, small sample volumes, etc. Nelson et al further teaches that although CE was originally carried out in capillary tubes, of increasing interest is the practice of using microchannels or trenches of capillary dimension on a planar substrate, known as microchannel electrophoresis (MCE) (column 1, lines 8-40). Therefore it would be obvious to use a capillary electrophoresis area, as taught by Nelson et al, in the cartridge of Wilding et al, in order to obtain rapid run times, high separation efficiency, and small sample volumes.

17. Claims 27-29, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Buechler et al [US 6,106,779] and Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Carlin [*Ultrasonics*, 1960, McGraw-Hill].

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With respect to claims 27, 28, 37, Wilding et al, Buechler et al, and Murphy et al do not specifically teach the use of a wall that is dome-shaped and convex, and sufficiently deflectable to deflect in response to vibratory movements.

However, it would be obvious to a person of ordinary skill in the art to use a wall that is dome-shaped and convex, as Carlin teaches the design of plastic lenses from glass, metals, and plastics such as plexiglass or polystyrene, in order to focus beams, which would be very valuable for agitational work, where a great amount of ultrasonic output is necessary (p. 89-90, 61-63). Therefore it would be obvious to use a wall that is dome-shaped and convex, as taught by Carlin, in the cartridge of Wilding et al, in order to focus beams, where a great amount of ultrasonic output is necessary.

18. With respect to claim 29, the Wilding et al teaches a device where the device ranges from microns to a few millimeters in thickness (column 4, lines 55-60).

19. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Buechler et al [US 6,106,779] and Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Bersted et al [US 6,129,879].

Wilding et al, Buechler et al, and Murphy et al, teach the use of lysing chambers, as discussed above. Wilding et al, Buechler et al, and Murphy et al do not specify that the lysing chamber comprises a wall comprised of a sheet or film of polymeric material

It is common to find PCR devices comprised of polymeric material such as polypropylene, since the surface of polypropylene is smooth and inert so does not readily bind enzymes and allows for easy recovery of products. Furthermore, Bersted et al teach that other advantages of polypropylene include low cost, ease of processing, strength, chemical inertness

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and hydrophobicity (column 1, lines 35-44). Therefore, it would be obvious to use a wall comprised by a sheet or film of polymeric material, as taught by Bersted et al, in the device of Wilding et al, since the surface of polymeric material does not readily bind to enzymes and allows for easy recovery of products.

20. Claims 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Buechler et al [US 6,106,779] and Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Lynnworth [US 4,335,719].

Wilding et al, Buechler et al, and Murphy et al teach the use of lysing chambers, but fail to teach the use of stiffening ribs.

Lynnworth, however, teaches that in order to increase the transmission through the shield at higher frequencies, or to reduce the mass of the shield, the shield thickness may be reduced considerably. Tube wall thickness as small as 0.1 mm are commonly available for many engineering materials. However, such thin walled tubes are not always adequate structurally, as their reduced stiffness is subject to vibratory motion. Therefore the thin shield is reinforced or stiffened in one direction by ribs (column 12, lines 20-30). Therefore, it would be obvious to use stiffening ribs in the invention of Wilding et al, as taught by Lynnworth, in order to increase the transmission through the wall at higher frequencies.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

22. Claims 21-30, 33-36, 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 18-24 of U.S. Patent No. 6,391,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because they share the same elements. The prior art teaches a device for use with an ultrasonic transducer to separate an analyte from a fluid sample, the device comprising a cartridge having a first flow path including a lysing chamber for lysing sample components to release the analyte therefrom, wherein the lysing chamber contains a membrane or filter for capturing the sample components as the sample flows through the lysing chamber, and wherein the lysing chamber is defined by at least one wall for contacting the transducer to effect the transfer of ultrasonic energy to the lysing chamber; at least a first waste chamber, downstream of the extraction chamber, for receiving waste fluid; an extraction chamber, downstream of the lysing chamber, the extraction chamber containing at least one solid support for capturing the released analyte; and at least one flow controller for directing the waste fluid into the waste chamber and for directing the eluted analyte into the second flow path (claims 1-8).

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With respect to claims 22-26, the prior art further teaches a mixing chamber and a reaction chamber in fluid communication (claims 15-16), as well as a capillary electrophoresis area (claim 18).

With respect to claims 27-30, 37, the prior art also teaches a wall that is dome shaped and convex, with a thickness of .025-.1 mm and comprising a sheet or film of polymeric material and stiffening ribs (claims 19-24).

With respect to claims 33-36, 40, the prior art teaches the use of beads and filters (claims 2-9)

Conclusion

23. No claims are allowed.

24. The following references are also cited as art of interest: Buechler et al [US 6,106,779] teach the use of meshes for lysing.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/14/09